

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of	)	<b>MAIL STOP PCT</b>
Nicholas S. Bodor et al.	)	Group Art Unit:
Application No.: 10/551,205	)	Examiner:
Filed: PCT/US2004/009387 filed	)	Confirmation No.: 4092
March 26, 2004	)	
For: ORAL FORMULATIONS OF	)	
CLADRIBINE	)	
	)	
	)	

**FIRST INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, the accompanying information is being submitted in accordance with 37 C.F.R. §§ 1.97 and 1.98. Applicants request the Examiner's consideration of the documents listed on the accompanying Form PTO-1449. All of these documents are cited in the instant specification, including the documents cited in the International Search Report (copy enclosed) which was issued in connection with PCT/US2004/009387, filed March 26, 2004, of which this application is the national phase.

Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed. However, copies of any listed U.S. patents and U.S. patent application publications are not enclosed since it is no longer required according to the July 11, 2003 waiver of the requirement for copies of cited U.S. patents and U.S. patent application publications in national patent applications filed after June 30, 2003 and international applications entering the national stage under 35 U.S.C. § 371 after June 30, 2003.

This Statement, Form PTO-1449 and documents are being submitted within three (3) months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later. Since these documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b), no fee or statement is required.

The following remarks are offered with respect to the listed documents which are not in English:

DE 31 18 218 is in German. Applicants do not have an English translation. However, an English abstract, together with the citation of the document in the instant specification, are provided to serve as a brief statement of relevance. Applicants consider this a general state of the art reference.

DE 33 17 064 is in German. Applicants do not have an English translation but provides herewith an English abstract. The abstract and citation of the document in the specification serve as a brief statement of relevance. Applicants consider this a general state of the art reference.

EP 0 149 197 B1 is in German, although the claims are also present in English. Applicants enclose a full English translation of this document, which is cited in the instant specification and which applicants consider to be a general state of the art reference.

It is respectfully requested that an Examiner-initialed copy of the accompanying Form PTO-1449 be returned to the undersigned.

Respectfully submitted,

BUCHANAN INGERSOLL AND ROONEY PC

Date: November 14, 2006

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Substitute for form 1449/PTO & 1449B/PTO		<i>Complete if Known</i>											
<b>FIRST</b> <b>INFORMATION DISCLOSURE</b> <b>STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>10/551,205</td> </tr> <tr> <td>Filing Date</td> <td></td> </tr> <tr> <td>First Named Inventor</td> <td>Nicholas S. Bodor</td> </tr> <tr> <td>Examiner Name</td> <td></td> </tr> <tr> <td>Attorney Docket No.</td> <td>0056192-000024</td> </tr> </table>		Application Number	10/551,205	Filing Date		First Named Inventor	Nicholas S. Bodor	Examiner Name		Attorney Docket No.	0056192-000024
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U.S. PATENT DOCUMENTS				
Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	4,383,992		Lipari	05-17-1983
	6,239,118	B1	Schatz et al.	05-29-2001
	5,424,296		Saven et al.	06-13-1995
	5,510,336		Saven et al.	04-23-1996
	5,506,214		Beutler	04-09-1996
	4,659,696		Hirai et al.	04-21-1987
	3,459,731		Gramera et al.	08-05-1969
	4,478,995		Shinoda et al.	10-23-1984
	5,310,732		Carson et al.	05-10-1994
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	6,194,395	B1	Schultz et al.	02-27-2001
	6,407,079	B1	Müller et al.	06-18-2002
	4,870,060		Müller	09-26-1989
	4,727,064		Pitha	02-23-1988
	4,596,795		Pitha	06-24-1986
	4,764,604		Müller	08-16-1988
	4,535,152		Szejtli et al.	08-13-1985

FOREIGN PATENT DOCUMENTS										
Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	STATUS					
					Translation	Partial Translation	Eng. Lang. Summary	Search Report	IPER	Cited in Spec
	0 197 571	A2	EP	10-15-1986						X
	90/12035	A1	WO	10-18-1990						X
	31 18 218	A1	DE	04-22-1982						X
	33 17 064	A1	DE	11-15-1984						X
	2 189 245	A	GB	10-21-1987						X
	0 149 197	B1	EP	07-24-1985	X					X
	0 094 157	A1	EP	11-16-1983						X

NON-PATENT LITERATURE DOCUMENTS	
Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Tarasiuk et al., "Stability of 2-Chloro-2'-Deoxyadenosine at Various pH and Temperature", Archivum Immunologiae et Therapiae Experimentalis, Vol. 42, pp. 13-15, 1994, published by Birkhauser Publishers Ltd., Basel, Switzerland
	Romine et al., "A Double-Blind, Placebo-Controlled, Randomized Trial of Cladribine in Relapsing-Remitting Multiple Sclerosis", Proceedings of the Association of American Physicians, Vol. 111, No. 1, pp. 35-44, 1999, published by Blackwell Publishing, Malden, MA

Examiner Signature	Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**FIRST**  
**INFORMATION DISCLOSURE**  
**STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 2

Application Number	10/551,205
Filing Date	
First Named Inventor	Nicholas S. Bodor
Examiner Name	
Attorney Docket No.	0056192-000024

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Tortorella et al., Current Opinion on Investigational Drugs, 2(12), pp. 1751-1756, 2001, published by PharmaPress Ltd., London, GB
	Selby et al., "Safety and Tolerability of Subcutaneous Cladribine Therapy in Progressive Multiple Sclerosis", Can. J. Neurol Sci., Vol. 25, pp. 295-299, 1998, published by Canadian Journal of Neurological Science, Calgary, Canada
	Rice et al., "Cladribine and progressive MS Clinical and MRI outcomes of a multicenter controlled trial", Neurology, Vol. 54, pp. 1145-1155, 2000, published by Lippincott Williams and Wilkins, Hagerstown, MD
	Liliemark et al., "On the Bioavailability of Oral and Subcutaneous 2-Chloro-2'-Deoxyadenosine in Humans: Alternative Routes of Administration", Journal of Clinical Oncology, Vol. 10, No. 10, pp. 1514-1518, 1992, published by American Society of Clinical Oncology, Alexandria, VA
	Karlsson et al., "Oral cladribine for B-cell chronic lymphocytic leukaemia: report of a phase II trial with a 3-d, 3-weekly schedule in untreated and pretreated patients, and a long-term follow-up of 126 previously untreated patients", British Journal of Haematology, Vol. 116, pp. 538-548, 2002, published by Blackwell Science Ltd., Oxford, UK
	Liliemark, "The Clinical Pharmacokinetics of Cladribine" Clin. Pharmacokinet, Vol. 32 (2), pp. 120-131, 1997, published by Adis International Limited, Wolters Kluwer Health, Yardley, PA
	Nakai et al., "Effects of Grinding on the Physical and Chemical Properties of Crystalline Medicinals with Microcrystalline Cellulose V: Comparison with Tri-O-methyl- $\beta$ -cyclodextrin Ground Mixtures", Chem. Pharm. Bulletin, Vol. 28(5), pp. 1552-1558, 1980, published by Pharmaceutical Society of Japan, Tokyo, Japan
	Saenger, "Cyclodextrin Inclusion Compounds in Research and Industry", Angew. Chem. Int. Ed. Engl., Vol. 19, pp. 344-362, 1980, published by Verlag Chemie, GmbH, Weinheim, Germany
	Tang et al., "Design of Freeze-Drying Processes for Pharmaceuticals: Practical Advice", Pharmaceutical Research, Vol. 21, No. 2, pp. 191-200, 2004, Springer, The Netherlands

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